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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/468,610	06/06/1995	SIMON C. BURTON	010055-134	5415

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[REDACTED] EXAMINER

WEBER, JON P

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1651

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/468,610

Applicant(s)

BURTON ET AL.

Examiner

Jon P Weber, Ph.D.

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 December 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5,7-23,55 and 56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5,7-23,55 and 56 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>31</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____ |

Withdrawal of Finality/ Status of the Claims

It is again argued that the double patenting rejection is in error and that the Office had previously determined that the '100 application was not material to patentability. Hence, it is argued that concluding that applicants failure to disclose the '100 application contravenes the duty to disclose is unjust to applicants. It is argued that even if the double patenting rejection is proper and applicants were required to disclose the conflicting application, the addition of the eight new references was not required by amendment. Accordingly it is urged that the finality is premature.

The double patenting rejection is discussed below. Further, there was never any disclosure of the '100 application in the '178 application or this application. The failure to disclose this possible double patenting situation is applicants'.

The newly added references were made in response to newly added claims 55-56 which recite specific ionizable ligands that had not previously been presented. To address these new limitations, it was necessary to demonstrate that resins having these specific functional groups appended were known in the art. Hence, the rejection was necessitated by amendment.

Thus, the argument that the final rejection is premature is not persuasive. The finality will not be withdrawn and the period for response continues to run from the date of mailing of the final Office action, instantly extended to four months.

Nevertheless, pursuant to discussions with the Group Director, Bruce Kisliuk, Supervisor, Michael Wityshyn, and Quality Assurance Specialist, Robert Hill, the Finality of the Office action of 21 June 2002 has been withdrawn and the Advisory action of 28 November 2002 has

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been vacated as a courtesy to Applicants but without admission that these Office actions were in error. Accordingly, the amendment filed 18 October 2002 has now been entered.

In the interview of 04 December 2002, Attorney asserted that the Cramer Declaration should have been considered. The record shows that the Cramer Declaration was considered and commented upon in the Office action of 21 June 2002.

Claims 1-5, 7-23, 55 and 56 have been presented for examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

Claims 1-5, 7-23 and 55-56 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 and 26-28 of U.S. Patent No. 5,652,348.

It is argued that the examiner in the conflicting patent did not raise a double patenting rejection even though the examiner was apprised of the parent application of the instant application, 08/268,178, in the response of 29 August 1995. It is also argued that this parent application was filed three months prior to the conflicting patent, hence the patent is not prior.

A review of the file history of the patent shows that parent application, 08/268,178, was brought to the examiner's attention in the context of prior art which had been cited in both the

patent and said parent. A copy of the initialed 1449 had not been provided with the Office action of 01 May 1995 and that was desired.

There is no evidence in the record to indicate that the examiner considered 08/268,178 for double patenting. The record suggests that the examiner simply provided signed and initialed copies of the 1449 with the final rejection of 18 December 1995 without any further comment.

Assuming, *in arguendo*, that the other examiner considered making a double patenting rejection, since the '100 application was ready for allowance while the instant application was pending, the MPEP states that the double patenting rejection should be dropped for the first application to issue. Hence, even if it had been made it would have been dropped. In either case the result would be the same.

That being said, the question remains to the validity of a double patenting rejection. Since, the basis of the rejection was not traversed, it is presumed that the reasons for making a double patenting rejection are acquiesced, that is, the instant claims are obvious over the patent.

With respect to the date of the parent being three months older than the patent, it is noted that a Terminal Disclaimer serves two purposes: 1) to assure that there is no improper term extension, and 2) to assure that both patents **remain** commonly owned.

Finally, when there is a double patenting issue between two copending applications it is Office practice to issue the first allowable application and make the obvious double patenting rejection in the other application.

Accordingly a double patenting rejection is proper and is maintained.

Claim Rejections - 35 USC § 112

Claims 55-56 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is argued that new matter is not present. Support for thiol and hydroxyl groups is alleged at least at page 24, lines 5-10. It is argued that this shows that these groups are reactive groups on the ligand. It is urged that these groups are ionizable groups within the meaning of the disclosure.

It is respectfully pointed out that the citation referenced establishes that these groups are used to link the ligand to the support matrix but are not themselves pendant after linking. The disclosure goes on to state, "In this resin, the ligand is attached through a stable thioether bond." The subsequent examples, such as mercaptobenzimidazole, make it clear that the thiol is used to link the ionizable ligand (e.g. an imidazole moiety) to the support but is not the ionizable ligand itself.

It is agreed that hydroxyls and thiols could be ionizable ligands, but the disclosure does not provide a positive recitation of these groups as ionizable ligands.

Applicant's arguments filed 18 October 2002 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 112, first paragraph is adhered to for the reasons of record and the additional reasons above.

Claim Rejections - 35 USC § 102

Claims 1-2, 4-5, 10-16, 18, 20 and 22-23 stand rejected under 35 U.S.C. 102(b) as being anticipated by Boardman et al. (1953).

The same arguments as raised in the response of 27 March 2002 are reiterated. It is asserted that the Declarations show that pH 6.1 is the pKa of the IRC-50 resin, so the resin is still 50% charged at this pH. It is asserted that the Declarations show that at pH 5.0 the resin retains a partial charge of 20%, which is greater than the "less than 5%" as required by the disclosure. It is urged that the experimental titration curve is more accurate than theoretical calculations of Henderson-Hasselbach. It is argued that Boardman fails to define "almost wholly undissociated." It is also argued that the rejection appears to rely upon Topp, Kunin, and Kitchener references and that the rejection should be under 103.

The most salient feature of Boardman, the titration curves shown in Figure 1, seems to have been overlooked. Clearly at pH 5.0, cytochrome C is bound, and elutes between pH values of 6-7 or 6-8 depending on ionic strength. Concomitantly, the resin takes up the sodium ions. Boardman also uses the resin to separate two carboxyhemoglobins with isoelectric points of 6.7 and 7.3 (Figure 2) at a pH of 5.8. The titration curve of the resin in the absence of protein may differ than with the protein. The arguments with respect to the Declarations have discussed in the Office action of 21 June 2002 and will not be restated. It is agreed that Boardman does not define the term "almost wholly undissociated", but taking its plain meaning suggests that the resin would meet the claim limitations. The Topp, Kunin, and Kitchener references were relied upon solely for their teachings of inherent properties, explanation of what the curves are

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showing, and for a larger figure of the titration curve of this resin. To assert that they are relied upon in an obvious type rejection is unwarranted.

Applicant's arguments filed 18 October 2002 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 102(b) is adhered to for the reasons of record and the additional reasons above.

Claim Rejections - 35 USC § 103

Claims 1-5, 7-23 and 55-56 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Boardman et al. (1953), Sasaki et al. (1979) and Sasaki et al. (1982) in view of Kunin (1958), Topp et al. (1949), Kitchener (1957) and Guthrie (1957) and further in view of Hancock et al. (US 4,401,629), Kitamura et al. (JP 01211543), Tokuyama (JP 60137441), Kondo et al. (JP 61033130), Iimuro et al. (US 4,950,807), Bruegger (US 4,810,391), Economy et al. (US 3,835,072), Jones et al. (US 4,154,676).

It is argued that the Board found that the Sasaki references do not obviate the instant claims because the references lack a resin that undergoes the transition between uncharged and charged between pH values of 5-9. It is urged that Sasaki references teach away because the resin they use suggests a pH value of 4.5 or less is necessary. It is urged that Sasaki references do not motivate substituting other resins. It is urged that Boardman teaches away too because it is only at "very low pHs" that the resin is fully charged. It is urged that the additional references teaching resins containing functional groups that may be ionizable fail to teach using these resins to purify proteins. Finally it is argued that combining fifteen references shows that the claimed invention is non-obvious.

The Board decision has been selectively interpreted. What the Board said is:

The examiner has asserted that “resins are known in the art which would be uncharged within the pH range of the scope of the claims.” However, the examiner has not favored the record with any evidence in support of this assertion. As the record now stands, the prior art does not describe any resin which meets the requirements of the claims on appeal. In other words, the claimed resins are novel. If the examiner is aware of resins “known in the art which would be uncharged within the pH range of the scope of the claims,” it is incumbent upon him to provide evidence in the record documenting the fact. The examiner has not done so.

It was solely on this basis that the rejection was not affirmed which is consistent with *In re Lee*, 61 USPQ2d 1430 (CAFC 2002). The Office action of 21 June 2002 provided the series of secondary references establishing the resins meeting the claim limitations were well known in the art. Specific examples of claimed functional groups pendant on the support were provided by these references. A large number of such references were cited to establish a large number of specifically recited functional groups. Hence, the record now clearly shows that such resins are well known in the art. It is not an assertion by the examiner as remarked by the Board. Further, the large number of references was provided solely for completeness. It was desirable to demonstrate that a large number of suitable functional groups were known in the art to be appended to supports.

Neither the Sasaki references nor Boardman teach away from the claimed invention. Sasaki provides a general concept and all of these three references merely provide specific examples. As is well known, the examples are non-limiting to the concept. They only provide working evidence of concept, unless there is some reason to believe the examples are the only possibility. In the instant case, the explanatory cartoon in Sasaki belies that suggestion. No specific pH values are given. Boardman is simply a specific example. They did not clearly contemplate the same concept as Sasaki.

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Applicant's arguments filed 18 October 2002 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 103(a) is adhered to for the reasons of record and the additional reasons above.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

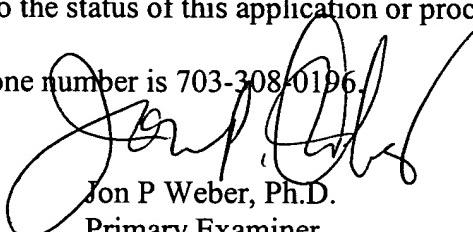
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

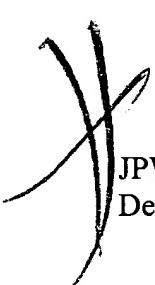
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P. Weber, Ph.D.
Primary Examiner
Art Unit 1651



JPW
December 24, 2002